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10/574,816

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

01/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/574,816

**Applicant(s)**

YUGE ET AL.

**Examiner**

Taeyoon Kim

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-23,25-28 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-18,20-23,25-28 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/27/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-5, 8-23, 25-28 and 45 are pending.

#### ***Response to Amendment***

Applicant's amendment and response filed on Sept. 27, 2007 has been received and entered into the case.

Claims 6, 7, 24 and 29-44 have been canceled, claim 45 is newly added, claims 5 and 19 have been withdrawn from consideration as being drawn to non-elected subject matter, and claims 1-4, 8-18, 20-23, 25-28 and 45 have been considered on the merits. All arguments have been fully considered.

The objection to the specification in the previous office action is withdrawn.

#### ***Information Disclosure Statement***

Applicant argued that the reference AM (EP 0489332) disclosed in the IDS filed on 4/6/2006 should be considered by the examiner since the international search report on PCT/JP03/16397 discloses the reference AM as "X" reference. Although it is correct that the disclosure of the reference in the international search report as "X" reference would be a proper way to provide concise explanation of relevance for non-English language reference, however, since applicant did not clearly indicate that the reference AM was cited as an "X" reference in the international search report in the IDS, it is not possible for the examiner to identify whether the reference was cited in the international search report. Therefore, the IDS, filed on 4/6/2006, is not considered proper. Upon the filing of new IDS with English translation on 9/27/2007, the reference (EP 0489332) has been considered by the examiner.

### ***Specification***

The abstract of the disclosure is objected to because the length of the abstract filed on 9/27/07.

MPEP § 608.01(b) states "the abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words. The abstract should not exceed 15 lines of text. Abstracts exceeding 15 lines of text should be checked to see that it does not exceed 150 words in length since the space provided for the abstract on the computer tape by the printer is limited."

Correction is required.

### ***Claim Objections***

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 14 depends on claim 8, which depends on claim 1. Since the limitations of claim 14 are identical to the limitations of claim 8, claim 14 is considered not to further limit claim 8. The limitation of claim 14 is having at least one other part besides the bag-type vessel with a gas permeable region. Since claim 1 discloses the main body is gas permeable, this limitation does not further limit claim 8.

Claims 17 and 18 disclose the phrase "discharged, or flows into, the vessel." It appears that there is a missing preposition in front of the term "the vessel". It would be more appropriate as "discharged from or flows into the vessel."

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 8-17, 22 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 17 and 27 disclose the quantity of an overall oxygen permeability being 1 mL/24 hr atm or more. It is not clearly what the value intends to claim because overall oxygen permeability in terms of volume is dependent on the size and thickness of the material measured from. Since there is no indication of any specific size of the claimed syringe-type device, there is no way to figure out the value of the gas permeability claimed in the claims. Even with lower gas permeability, if the total area and thickness of the region is large enough, it will have the same overall permeability compared to the higher gas permeability region with smaller and thinner material. Clarification is required.

Claim 8 discloses the term "cylindrical exterior". It is not clear whether the term is different from the main body (barrel) of the syringe-type device in claim 1. In other word, it is not clear whether the cylindrical exterior part is required in addition to the main body of the device, or it is the same part of the device.

Claim 15 discloses the phrase "for rupturing the bag-type vessel when the bag-type vessel is being stored in ..." It is not clear whether the phrase intends to claim that whenever the bag-type vessel being inside of the device, it would be ruptured by the

rupturing means, or the rupture of the vessel requires pressure to the plunger of the device (sliding of the plunger). It appears that the vessel is ruptured when the pressure is applied to the device, not just being stored in the device would not rupture instantaneously. Clarification is required.

The phrase "in a sliding direction of the plunger" in claim 22 does not clearly point out what the subject matter is. If the portion of gas permeable region, as claimed in the current claim, is in the main body of the device, it would be considered to be a sliding direction of the plunger. It appears that the limitation is not simply claiming any place on the main body. Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-18, 20, 22, 25-28 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pickhard (US 5,147,311) in light of Dow Corning article (Rubber Physical and Chemical Properties;  
[http://www.dowcorning.com/content/rubber/rubberprop/rubber\\_perm.asp](http://www.dowcorning.com/content/rubber/rubberprop/rubber_perm.asp)).

Claims 1-4, 8-18, 20, 22, 25-28 and 45 are drawn to a syringe-type cell handling device comprising a vessel comprising a main body and a plunger to form a syringe type device, and at least part or a whole of the main body or plunger being gas permeable; a limitation to the gas permeable region having 1 mL/24 hr atm or more of

oxygen permeability; a limitation to the gas permeable region being composed of a gas permeable resin or porous film; a limitation to the main body comprising a flexible and gas-permeable bag-type vessel detachable from a cylindrical exterior (the main body); a limitation to the bag-type vessel comprising a discharge part and a push part; a limitation to the bag-type vessel having a concertina section; a limitation to the bag-type vessel being a tube; a limitation to the device further comprising a rupturing means for rupturing the bag-type vessel; a limitation to the device having a discharge part attachable with a needle, a catheter or other conduit.

Pickhard teaches a syringe device having a housing (main body; vessel), slidable plunger (piston; a volume varying means), a frontal end region (discharge part; a mouth part) linked an injection needle, a deformable ampoule (a contractible bag-type vessel) having a concertina section (see part #14 of Fig. 1 and 11), which can be ruptured by a piercing device (part #30 of Fig. 11). Pickhard also teaches the material for the deformable ampoule being pharmaceutical rubber, plastic or silicone (see column 8, lines 15-21), and other parts of the injector (syringe device) is made of rigid plastic (e.g. part #15, 18; column 8, lines 21-24 and 53-55). Since silicone is well known in the art as a gas permeable material as supported by the Dow Corning article (see the Table of Permeability rate of silicone rubber).

Although Pickhard does not teach the intended use of the device to hold handling medium containing cells, the examiner takes the position that since the device of Pickhard is considered to the same as the claimed invention, the device of Pickhard is capable of holding cells in a medium.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "to hold, in a liquid-tight stat, a handling medium that is fluid and contains cells" does not affect the patentability of the claimed product/composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

With regard to the limitation of oxygen permeability, since plastic is well known in the art to be oxygen permeable, the examiner takes the position that the plastic material used in Pickhard would have inherently met the limitation of quantity of the gas permeability in terms of overall oxygen permeability claimed in claims 3, 17 and 27.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' gas permeable material differs, and if so to what extent, from the plastic material (a gas permeable resin) discussed in Pickhard. Accordingly, it has been established that the prior art material demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed material for gas permeability region that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known plastic material is not disclosed in a reference does not make the known plastic material patentable. The new material

possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the plastic of the cited prior art do not possess a critical characteristic that is possessed by the claimed gas permeable resin, would advance prosecution and might permit allowance of claims to applicants' device.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-18, 20-22, 25-28 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickhard (supra) in view of Dow Corning article (supra) in further view of Karakashian (US 3,937,219) or Polak (US 5,114,421).

Claims 1-4, 8-18, 20-22, 25-28 and 45 are drawn to a syringe-type cell handling device comprising a vessel comprising a main body and a plunger to form a syringe type device, a handling medium containing cells, and at least part or a whole of the main body or plunger being gas permeable; a limitation to the gas permeable region having 1 mL/24 hr atm or more of oxygen permeability; a limitation to the gas permeable region being composed of a gas permeable resin or porous film; a limitation to the main body comprising a flexible and gas-permeable bag-type vessel detachable from a cylindrical exterior (the main body); a limitation to the bag-type vessel comprising a discharge part and a push part; a limitation to the bag-type vessel having a concertina section; a limitation to the bag-type vessel being a tube; a limitation to the device further

comprising a rupturing means for rupturing the bag-type vessel; a limitation to the device having a discharge part attachable with a needle, a catheter or other conduit.

Pickhard teaches a syringe device having a housing (main body), slidable plunger (a volume varying means), a frontal end region (discharge part; a mouth part) linked an injection needle, a deformable ampoule (a contractible bag-type vessel) having a concertina section (see part #14 of Fig. 1 and 11), which can be ruptured by a piercing device (part #30 of Fig. 11). Pickhard also teaches the material for the deformable ampoule being pharmaceutical rubber or silicone (see column 8, lines 15-21). Since silicone is well known in the art as a gas permeable material as supported by the Dow Corning article (see the Table of Permeability rate of silicone rubber).

Pickhard is silent of the gas permeable region on a main body extending in a sliding direction of plunger.

Karakashian teaches that a barrel of a syringe device is made of plastic, which is inherently gas permeable (see column 3, lines 44-51).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to make the syringe device of Packard having a main body (barrel) being gas permeable.

The skilled artisan would have been motivated to make such a modification because Karakashian teaches that having the barrel gas-permeable, it would be efficient to sterilize the device by gas sterilization to prevent contamination. Such modification would inherently meet the limitation of intended use of the device in cell handling.

The person of ordinary skill in the art would have had a reasonable expectation of success in making the main body or barrel of Pickhard's syringe device to be gas permeable.

Furthermore, it is noted that it is extremely well known in the art that majority of syringe device is made of plastic and thus gas permeable. Therefore, it would have been obvious to person of ordinary skill in the art to try to make the barrel of Pickhard's device with plastic resin because there are a finite number of gas permeable material available for making a syringe barrel, and plastic material or plastic resin is common material known in the art for such purpose.

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

Although Pickhard does not teach the device comprising a handling medium containing cells, it would have been obvious to a person of ordinary skill in the art to use the device of Pickhard for a cell handling purpose. This is because it is well known in

the art that a device like Pickhard's syringe is commonly used for withdrawing blood (cells in medium) from a patient or inject cells during cell transplantation to a patient in need thereof. Furthermore, since the device of Pickhard is considered to the same as the claimed invention, and a person of ordinary skill in the art would recognize that the device of Pickhard is capable of holding cells in a medium, the examiner takes the position that it would have been obvious to a person of ordinary skill in the art to use the device for cell handling for cell implantation or delivery, and therefore the reference renders the claimed invention obvious.

With regard to the modification to the mouth (discharge part) of the device being covered with a closing member, or connected with a catheter or other conduit, it is well known in the art that any syringe type device would be capable of being connected to other conduit or a catheter, and using a cap to close the opening at the end of the discharge part. In fact, Pickhard discloses a coupling component communicating with hypodermic needle by way of flexible tubing (catheter or conduit) (see column 16, lines 23-26). Furthermore, Polak teaches a fitted cap to close the opening at the end of the syringe barrel (see column 11, lines 12-14; and Fig. 5, #127).

With regard to the limitations of claims 20-22 that the multiple locations of gas permeable region on the main body which extends in a sliding direction of the plunger and the gas permeable region having higher gas permeability than the principal material of the main body, the teaching of Karakashian indicates that the whole main body is made of plastic and therefore considered to have gas permeable region at a sliding direction of the plunger.

However, Pickhard in view of Karakashian do not teach differential permeability of the gas permeable region and the main body.

Polak teaches a syringe barrel having a region (a hole) made of gas permeable membrane (see Fig. 7-9), which is a liquid-impervious and gas permeable semi-permeable membrane (see column 7, lines 4-26), and therefore it is considered to be porous film and apparently having higher gas permeability than the plastic material of Karakashian.

Therefore, it would have been obvious to a person of ordinary skill in the art to use the barrel of Polak's syringe in the syringe device of Pickhard in view of Karakashian. This is because the syringe of Polak is considered as an art-accepted equivalent to the Karakashian. Furthermore, the gas-permeable membrane of Polak provides pressure equalization and thereby relieves the back pressure, while maintaining a sterile environment in syringe assembly (see column 11, lines 55-63). Therefore, the addition of gas-permeable membrane hole to the syringe of Pickhard

Although Polak does not particularly teach the shape of the hole having gas permeable membrane extending in a sliding direction of the plunger, it would have been obvious to a person of ordinary skill in the art to try various different shapes or number of holes made in the main body.

With regard to shape change, M.P.E.P. §2144.04 states "In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular

configuration of the claimed container was significant.).”

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pickhard (supra) in view of Dow Corning article (supra) in further view of Karakashian (supra), Polak (supra), and Baidwan et al. (US 4,299,238).

Claim 23 is drawn to a limitation to the cell handling device of claim 22 wherein the gas permeable region is formed at a tip of the plunger.

Pickhard in view of Dow Corning article, in further view of Karakashian and Polak teach the limitation of claim 22.

Pickhard in view of Dow Corning article, in further view of Karakashian and Polak do not teach the gas permeable region being formed at a tip of the plunger.

Baidwan et al. teach a vented piston (see Abstract and Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the piston of Baidwan et al. in the syringe device of Pickhard in view of Dow Corning article, in further view of Karakashian and Polak.

The skilled artisan would have been motivated to make such a modification because the vented piston of Baidwan et al. is to exhaust the air while pushing the piston, and it is considered the same purpose as the gas permeable region on the main body (barrel) of Polak. Thus, a person of ordinary skill in the art would be motivated to

use the vented piston of Baidwan et al. to further facilitate pressure equalization to relieve back pressure with reasonable expectation of success.

Since the gas permeable region formed at the tip of the plunger of Baidwan et al. is for the same purpose as the gas permeable region of Polak, it would have been obvious to combine these two components for the syringe of Pickhard in view of Dow Corning article, in further view of Karakashian and Polak.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

**Conclusion**

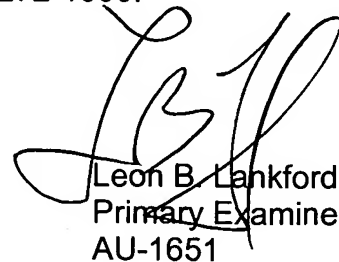
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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